Word Count: 9,845

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

THE CITY AND COUNTY OF SAN FRANCISCO, CALIFORNIA and THE PEOPLE OF THE STATE OF CALIFORNIA, Acting by and through San Francisco City Attorney DAVID CHIU,

Plaintiffs,

v.

PURDUE PHARMA L.P., et al.

Defendants.

Case No. 3:18-cv-7591-CRB

DECLARATION OF CARMEN A. CATIZONE, M.S., R.PH., D.PH.

TABLE OF CONTENTS

I, Carmen A. Catizone, under penalty of perjury declare as follows.

1. My relevant education and experience are contained in my CV, attached to this declaration as Exhibit A.

2. Of particular note, I practiced as a registered pharmacist for twenty years. I also served as the Executive Director and CEO of the National Association of Boards of Pharmacy ("NABP")—an impartial organization consisting of state agencies that regulate the practice of pharmacy. Throughout my career, I have taught classes at and liaised with many federal agencies, including the DEA and the FDA. I have also testified as an expert in legislative hearings, DEA enforcement actions, and civil trials—including in the recent opioids trial before Judge Polster.

3. The opinions presented are based on my experience and expertise in the practice and regulation of pharmacy.

I. THE PRACTICE OF PHARMACY—STANDARD OF CARE

4. The practice of pharmacy is governed by well-defined laws and regulations, both at the national and state-wide levels. It is also subject to well-established standards of care, including requirements for the careful evaluation of prescriptions and efforts to guard against the diversion of dangerous medications into non-medical or illegitimate use.

5. In regulating pharmacy practice, federal and state law complement each other. Federal law establishes the closed system of distribution, explained below, and through this system supports and enforces state standards of care, which are established by state statutes, regulations, boards of pharmacy, and professional norms.

A. Closed System of Controlled Substances

6. The Comprehensive Drug Abuse Prevention and Control Act of 1970 ("Controlled Substances Act" or "CSA"), 21 U.S.C. § 801 *et seq.* was put in place to create a closed system for the distribution of controlled substances to prevent the theft and diversion of dangerous substances. Under the CSA, drugs are classified into schedules depending upon the drug's accepted medical use and abuse potential. Schedule I drugs have a high potential for abuse, no currently accepted medical use, and may not be

prescribed for any purpose. Schedule II drugs also have a high potential for abuse, with use potentially leading to severe psychological or physical dependence, but these drugs have accepted medical uses and may be prescribed in accordance with the safeguards of the CSA. Drugs classified as Schedule III and Schedule IV have, respectively, moderate and low potential for abuse and dependence.

7. Drugs listed on Schedule II are the most dangerous drugs that may be dispensed and thus represent those for which the greatest vigilance in dispensing is required. Nearly all prescription opioids, including formulations containing oxycodone, hydrocodone, hydromorphone, and fentanyl, are currently listed on Schedule II and pose a significant risk to the public.

8. Given those risks, good pharmacy practice dictates that several safeguards be established to ensure that controlled substances are dispensed only to patients holding a valid prescription issued by a DEA-licensed practitioner acting within the usual course of the practitioner's professional practice. This requirement for safeguards is also reflected in federal and state laws.

9. The CSA also creates a "closed system" in which distribution may lawfully occur only among registered handlers of controlled substances, referred to as "registrants." DEA, 75 Fed. Reg. 16235, 16237 (Mar. 31, 2010). This closed system allows for controlled substances to be traced from initial manufacture to final dispensing: registered manufacturers may sell only to registered dispensers or registered wholesalers, who in turn may sell only to registered dispensers, who must dispense in accordance with the requirements of the statute and regulations.

10. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). Within the structure of the closed system, pharmacies are the last line of defense. For that reason, pharmacies and pharmacists must ensure that prescriptions for controlled substances are issued for legitimate medical purposes, within the scope of the prescriber's practice, and not being abused or diverted.

11. Dispensing drugs for illegitimate purposes, or under circumstances which a pharmacist otherwise knows or should know present a significant risk for diversion, is illegal under the CSA and falls outside the defined practice of pharmacy and standards of care.

B. Corresponding Responsibility

12. A primary tenet of the standard of care in the practice of pharmacy is a pharmacist's independent responsibility to ensure that all prescriptions are issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice. In addition, 21 C.F.R. § 1306.04 provides that, although the practitioner is responsible for the proper prescribing of controlled substances, the pharmacist also has a *corresponding responsibility* regarding the dispensing of a prescription. Moreover,

> An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of [the CSA] and the person knowingly filling such a purported prescription … shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a). This section is understood to require a pharmacist to determine, prior to filling a prescription for a controlled substance, if that prescription is valid and issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice.

13. The DEA has, for decades, consistently held pharmacies and pharmacy corporations responsible for failing to exercise their corresponding responsibility under the CSA. In other words, "[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself."[1] This means that a chain pharmacy like Walgreens cannot abdicate its responsibilities to its individual pharmacists and must provide them with the tools, training, and time to ensure compliance with the CSA.

[1] P-42147: *Holiday CVS, LLC*, 77 Fed. Reg. 62316-62346, at 62341 (Oct. 12, 2012).

14. Relatedly, pharmacies have a duty to ensure compliance with the law. This includes creating a culture that encourages pharmacists to exercise their professional judgment, supports them when they decline to fill prescriptions, and prioritizes patient and community safety over profit.

15. A pharmacist or pharmacy who "filled a prescription notwithstanding her actual knowledge that the prescription lacked a legitimate medical purpose" or who "was willfully blind or deliberately ignorant to the fact that the prescription lacked a legitimate medical purpose" violates the corresponding responsibility requirement.[2]

C. Red Flags

16. To satisfy the corresponding responsibility requirement, pharmacies and pharmacists must recognize, investigate, and resolve signs of a prescription's invalidity (red flags) "arising during the presentation of a prescription which creates a reasonable suspicion that the prescription is not, on its face, legitimate."[3] Red flags are objective warning signs which may indicate that activities are occurring outside the usual and customary scope of pharmacy practice—activities that are suggestive of abuse, diversion, and fraudulent acts.

17. Red flags are known concepts in pharmacy practice as well as the subject of DEA guidance and enforcement, guidance from state Boards of Pharmacy, negotiated consensus documents published by the NABP, and by industry trade groups such as the National Association of Chain Pharmacies.

18. The table below identifies certain established flags. For each, I have provided a brief description (with illustrative citations to Walgreens' awareness of them), as well as the specific parameters of the corresponding numbered flags used in the analysis of Walgreens' dispensing data by Dr. Craig McCann, which I endorse.

---

[2] P-22219: *Pharmacy Doctors Enterprises*, 83 Fed. Reg. 10,876, 10,896 (DEA Mar. 13, 2018).

[3] *United States v. City Pharmacy, LLC*, No. 3:16-CV-24, 2017 WL 1405164, at *4 (N.D. W. Va. Apr. 19, 2017); *see also United States v. Lawson*, 682 F.2d 480, 483 n.6 (4th Cir. 1982).

SUBJECT	DESCRIPTION	FLAG NO.[4]
Long distance travel	Patients traveling long distances to their pharmacy or prescriber	(1) An opioid was dispensed to a patient who traveled more than 25 miles to visit the pharmacy. (2) An opioid was dispensed to a patient who traveled more than 25 miles to visit their prescriber.
Doctor-shopping	Patient obtaining multiple opioid prescriptions from different prescribers[5]	(3) Patient was dispensed opioid prescriptions with overlapping days of supply that were written by two or more prescribers
Pharmacy-shopping	Patient traveling to multiple pharmacies to fill opioid prescriptions[6]	(4) Patient was dispensed opioid prescriptions with overlapping days of supply at two or more pharmacies
Drug Cocktail	Prescriptions for an opioid and benzodiazepine, with or without an additional muscle-relaxer,[7] which, when combined, intensifies the risk of overdose and death	Patient was dispensed: (5) An opioid, a benzodiazepine, and a muscle relaxer for overlapping days of supply (6) An opioid, a benzodiazepine, and a muscle relaxer on the same day, and all the prescriptions were written by the same prescriber (7) An opioid and a benzodiazepine within 30 days of one another (8) An opioid and a benzodiazepine on the same day, and both prescriptions were written by the same prescriber
Excessive dispensing	Prescription(s) for an excessive quantity of an opioid, or multiple opioids, on the same day or within an	(9) Patient was dispensed two short-acting opioid drugs on the same day (11) Patient was dispensed an opioid prescription of over 200 MME per day on or before December 31, 2018 or over 90 MME per day after December 31, 2018

[4] Dr. McCann's initial report identifies 16 flags. I endorse all of them. However, for simplicity's sake, I have reduced the number to 14 but preserved the original numbering.

[5] P-17169_00011.

[6] *Id.*; P-20790_00016.

[7] P-15314_00027; P-19595_00010.

SUBJECT	DESCRIPTION	FLAG NO.[4]
	overlapping period of time[8]	(15) A patient was dispensed more than 210 "days of supply" of all opioids combined in a 6-month period
Pattern prescribing	"[A] [p]rescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals."[9]	(12) An opioid was dispensed to at least 4 different patients on the same day and the opioid prescriptions were for the same base drug, strength, and dosage form and were written by the same prescriber
Early refills	An individual "[c]onsistently requests … early refills" or "routinely attempts to obtain an early refill on controlled substances."[10]	(14) An opioid prescription was refilled more than 5 days before the patient's previous prescription should have run out
Cash payment	A patient "pay[s] by cash or by using a cash discount card (in a possible attempt to circumvent third party billing restrictions)."[11]	(16) A patient was dispensed an opioid and paid cash.

19. These flags—and others—are widely recognized in pharmacy practice nationwide as warning signs of potential diversion.[12]

20. It is critical that all pharmacy personnel be trained to identify and address these indicators of potential diversion.

---

[8] *E.g.*, P-19595_00009-10 (Pharmacist GFD Review training); P-15074_00003 (GFD policies).

[9] P-17169_00010.

[10] P-19595_00009.

[11] P-15314_00028.

[12] *Holiday CVS*, 77 F.R. 62341; *East Main Street*, 75 F.R. 66149-01; *Pharmacy Doctors Enterprises*, 83 F.R. 10,896; P-23068, Stakeholders' Challenges and Red Flag Warning Signs; P-21866, California BOP, Corresponding Responsibility Pamphlet (https://www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf.).

21. A pharmacy should also be reviewing available data to assess, among other things, prescribers, patients, and pharmacies which trigger these red flags.

22. Each red flag is a potential indication of diversion, and when a prescription is presented with multiple red flags, the likelihood of diversion increases greatly.

1. Red Flag Investigation, Resolution, and Documentation

23. Pharmacy standards of care, boards of pharmacy, and the DEA mandate that due diligence be performed and that each red flag must be resolved before a prescription is dispensed.

24. The four guiding elements of due diligence are: *identification* of all red flags; *collection* of all relevant information; *evaluation* of the information; and *documentation* of the reasons supporting dispensing.

25. The importance of the first three is self-evident. Documentation is also critical. It explains how the pharmacist resolved red flags or why the pharmacist refused to fill the prescription so that the same or other pharmacists can make use of the information when filling future prescriptions from the same doctor or the same patient. Documentation also affords the pharmacy the opportunity to review, audit, and investigate whether red flags are being identified and appropriately resolved, and it assists regulators if there is a need to investigate potential diversion.

26. Adequate due diligence shows one's work and must clearly explain the specific concerns identified, the information evaluated, and the reasons for dispensing. Comments such as "called doctor," "checked PDMP," or "consulted patient" do not meet the requirement to fully document how the specific red flag was resolved prior to dispensing the medication.

27. In situations where diversion is suspected, the pharmacies must alert the authorities, document the facts, and refuse to fill.

D. Drug Utilization Review (DUR) Process and Prescription Drug Monitoring Programs (PDMPs)

28. The DUR process is a foundational component of pharmacy practice. It requires pharmacists to ascertain the appropriateness of a patient's medication, including verifying that the dosage and duration is correct, does not conflict with allergies or individual characteristics, does not interact with other medications, and that the patient is not abusing the medication. These roles and duties were codified in the Omnibus Budget Reconciliation Act of 1990, which included four components: (1) Prospective Drug Use Review, (2) Retrospective Drug Use Review, (3) Assessment of Drug Use Data, and (4) Educational Outreach Programs.

29. The DUR process is especially important for the assessment of the appropriateness of prescribed controlled substances. Such an assessment should examine over-utilization, inappropriate duration of treatment, drug interactions, and therapeutic duplication in order to provide appropriate care and identify abuse and misuse of these dangerous drugs. Identification and resolution of the red flags discussed above is part of the DUR process.

30. However, states realized that the general DUR provisions were not effectively preventing the escalation of opioid abuse and increased their support for, and reliance on, PDMPs.

31. A PDMP is an interactive database that facilitates the sharing of health information related to controlled substance prescriptions. PDMPs provide clinicians with information on a patient's controlled-substance prescription history and can be a useful tool when considering treatment options and screening patients who may be at risk for abuse or diversion. Chain pharmacies, along with independents, are the primary sources of the data contained within a PDMP and play a critical role in ensuring that complete and comprehensive data is provided so as to contribute to the usefulness of the database.

32. As rates of PDMP participation increase, measures of doctor-shopping and prescribing of certain controlled substances decline. The data suggest that PDMP

utilization helps to promote medically warranted prescribing and dispensing, and assists in detecting possible controlled substance misuse and diversion.

33. California initiated its prescription monitoring program in 1939, beginning the "paper era" of PDMPs. State PDMPs continued to grow through the 1990s and 2000s to help combat the growing opioid epidemic. California's current PDMP is the Controlled Substance Utilization Review and Evaluation System (CURES).

E. Walgreens' Responsibilities as a Major Chain Pharmacy

34. Large chain pharmacies, like Walgreens, have a special responsibility based on the outsized impact of their policy decisions on the communities they serve and on the wealth of data they collect that gives them a unique window on the prescribing practices in their community, including data that permits the identification of high-volume or otherwise suspicious prescribers, and outlier pharmacies, pharmacists, and patients. It is particularly important, therefore, that they maintain robust compliance programs and regularly audit their practices to ensure they do not become major sources of drug diversion. Chain pharmacies like Walgreens thus have an obligation to provide their pharmacists with the tools, training, and time necessary to meet their responsibilities in prescribing dangerous, controlled substances.

II. WALGREENS DID NOT MEET THE STANDARD OF CARE

35. Based on my extensive review, I have concluded that Walgreens failed to maintain effective controls to guard against diversion and failed to meet the standard of care for pharmacies dispensing controlled substances.

A. Walgreens' Due Diligence Policies Were Inadequate

36. Under the CSA and under prevailing standards of pharmacy practice, pharmacies have an obligation to ensure that its pharmacists have the training, tools, and time to: (a) accurately identify all red flags; (b) investigate those flags; (c) independently evaluate the collected information; and (d) clearly document their analysis and decisions.

37. For several years of the opioid epidemic, Walgreens required almost none of that. Although Walgreens' policy in 1998 stated that if a pharmacist could not clear red

flags, the pharmacist should "[n]ot dispense the drug,"[13] from 2003 to 2012, its policy simply instructed pharmacists to call the prescriber. If the prescriber said the prescription was valid, Walgreens' pharmacists were to "process the prescription as normal."[14] This was plainly inadequate because, while some flags can be cleared in a conversation with a prescriber, many others—e.g., doctor-shopping, pharmacy-shopping—cannot. This is especially true for physicians who were not prescribing for legitimate medical purposes or have been duped by patients shopping for drugs for non-medical use. Testimony about this time-period further confirms pharmacists' understanding that, at Walgreens, it was "not their job" to meaningfully investigate prescriptions and if "[t]hey have a script, they will fill it."[15]

38. The DEA took note of Walgreens' policy failures. In 2009, the DEA issued an Order to Show Cause alleging that:

> Since at least January 2007, Walgreens distributed controlled substances to individuals located in California based on purported prescriptions issued by physicians who were not licensed to practice medicine in California. … [CURES] data reveals that Walgreens also dispensed controlled substances to individuals that Walgreens knew or should have known were diverting the controlled substances. … By dispensing such prescriptions, Walgreens failed to fulfill its corresponding responsibility… .[16]

39. Walgreens settled the matter in April 2011 and agreed to strengthen its diversion controls through more robust policies and more frequent training.[17]

40. But in 2012, the DEA issued another Order to Show Cause again identifying Walgreens' widespread failure to comply with the CSA.[18] The 2012 enforcement action

---

[13] P-19745_00002.

[14] *See, e.g.*, P-19613_00012; P-15119_00011; P-15188_00002.

[15] Lucas, Kristine FL AG Trial Tr. (4/12/22) 103:10-11; *see also* Gayle Dep. 16-17 (Walgreens pharmacists in San Francisco felt "a pressure to fill, fill, fill and that was what the company cared about most.").

[16] P-20642_00001-02.

[17] P-19651.

[18] P-19716.

addressed conduct in Florida, but, as Walgreens well understood, it "[wa]sn't just a Florida problem."[19]

41. Those enforcement actions and subsequent interactions with the DEA confirmed what Walgreens should have already known: the company should never have simply "rel[ied] on [] 'I spoke to the prescriber and he said it was okay.'"[20] Again, as a result, Walgreens agreed to take several actions, including revamping its opioid dispensing policy.

42. However, the new policies remained deficient in many ways. For example, beginning in April 2013,[21] Walgreens' written policy required its pharmacists to complete a Target Drug Good Faith Dispensing ("TDGFD") checklist of due diligence tasks[22] in order to put "put teeth around GFD for high-risk products."[23]

43. This checklist, however, was required for just three "Target Drugs": single-ingredient Oxycodone, Hydromorphone, and Methadone.[24] This means that highly prescribed and abused combination drugs like Percocet (oxycodone/acetaminophen) were not included. Also excluded was hydrocodone, which was in the process of being reclassified as a Schedule II drug.[25] Hydrocodone was rescheduled in 2014, but, to this day, Walgreens has not made it a Target Drug, meaning that drugs like Norco, Vicodin, and other highly prescribed and diverted opioids are not subject to the checklist requirement at all.

44. The checklists were also difficult for future dispensing pharmacists to use in conducting their own due diligence. Until 2020, the checklists were maintained only on

---

[19] P-00136_00028 (speaker notes).

[20] P-20639_00009.

[21] P-17177; P-17188.

[22] P-15307_00013-14; P-15310_00042-44.

[23] P-20799_00001.

[24] P-15037_00010; P-15038_00003.

[25] P-26350.

paper.[26] When they were finally converted to electronic format, Walgreens' Vice President of Pharmaceutical Integrity, Tasha Polster, commented, "I have been wanting to do this since day one and [Walgreens' President of Pharmacy Health and Wellness] wouldn't let me."[27] Furthermore, the checklists were filed numerically according to prescription number and not organized by patient.[28] This made them difficult to find even in the stores where they were kept.

45. Several other policy changes were improvements, at least on paper. For example, Walgreens directed its pharmacists to review the patient's prescription history on the state PDMP.[29] Pharmacists were also encouraged to leave comments when resolving all major DUR alerts, so that their "peers [are] able to understand what occurred should they need to revisit."[30] Similarly, a later training document stated: "It is important that notes left are clear concise and understandable by anyone who is taking over the patient's care after the end of your shift or reviewing the patient's profile for a future fill of the medication."[31]

46. The documentation requirement was not limited to DUR resolutions. In fact, Walgreens' formal policy from 2012 onward explains: "It is imperative that pharmacists document all efforts used to validate good faith dispensing."[32] As the revised policy recognizes, documenting due diligence is indeed critical. It is particularly important to document refusals to fill so that other pharmacists are aware of the potential for diversion from either the patient or the prescriber.

47. Nonetheless, despite the formal recognition of the importance of storing information in a manner easily accessible to all its pharmacists, Walgreens' primary

---

[26] CT3 Arends Dep. 99-100.

[27] P-20795_00001.

[28] CT3 Polster Dep. 57-58.

[29] P-15314_00026.

[30] CT3 Polster Dep. 406-07; P-25751_00014.

[31] P-17247.

[32] P-15314_00028.

method of documenting refusals to fill was still in hard copy, which, as with the paper TDGFD checklists, are not easily accessible within one store and inaccessible across the chain.

48. The proper means of recording a refusal to fill in a chain pharmacy like Walgreens is in an electronic system shared with all pharmacy staff. Walgreens' dispensing policy has never been clear as to how (or even whether) a pharmacist should document a refusal to fill in the computer system.[33] Starting in 2012, Walgreens instructed pharmacists to record refusals to fill within patients' profiles in the computer—but only for three specific drugs.[34] Those notes, however, were infrequently reviewed and—because they were located in a patient-, not prescriber-specific profiles—could not easily be used to alert pharmacists to suspicious prescribers. The comments fields also accepted a limited number of characters and, in April 2013, Walgreens' solution to the resulting space constraint was to "delete older comments or refusals from the patient profiles," thereby depriving pharmacists of useful information about prior refusals to fill.[35] I attended an inspection of Walgreens' IC+ computer system which confirmed that, as recently as this year, Patient and Prescriber Comments were limited to 320 and 160 characters respectively (including spaces). For comparison, the preceding sentence includes 191 characters.

B. Walgreens Did Not Provide Its Pharmacists the Proper Time, Training, or Tools to Prevent Diversion

49. Below I analyze how Walgreens' policies and procedures failed in practice. In doing so, I rely on Walgreens' corporate testimony and documents. Many of these failures are further confirmed by the on-the-ground experiences of Walgreens' own pharmacists, which I summarize in a later section.

---

[33] *See* P-19745_00002 (8/1998 policy); P-15119_00003 (3/2003 policy); P-15176_00001 (6/2006 policy); P-15314_00026 (6/2012 policy); P-15074 (2016 policy).

[34] P-20789_00037; *see also* CT3 Arends Dep. 99-100.

[35] P-20801_00001; *see also* CT3 Polster Dep. 319-29.

1. Walgreens Did Not Perform Sufficient Audits, and Those It Did Perform Revealed Widespread Non-Compliance

50. The limited audits Walgreens conducted on due diligence practices indicate that compliance was poor.[36] For example, a December 2014 audit revealed that there was no formal monitoring program to confirm that pharmacies across the chain were complying with controlled substance documentation requirements, no monitoring outside of a limited "store walk program," no corporate reporting was being generated, and employees were failing to timely complete GFD training, such that, at the time of the audit, over 35,000 employees had not completed their required training for that year.[37]

51. In 2015, Walgreens performed an audit of a random sample of approximately 2,400 pharmacies—about a quarter of its pharmacies—to determine whether it was "compliant with the policies/procedures put in place" regarding dispensing, following its settlements with the DEA.[38] It was not. As the audit progressed, Vice President of Pharmaceutical Integrity, Tasha Polster, remarked "put your seat belts on" because the audits were "not going great" and they would need to implement a "mitigation plan … to satisfy the MOA."[39] Fewer than 60% of stores were complying with the Target Drug checklist requirement. And, over a nine-month period, 1,160 stores (48%) had not refused a single prescription, 1,182 stores (49%) had refused fewer than 25 prescriptions, and only 63 stores (3%) had refused 26 or more prescriptions.[40] In certain cases, the pharmacists were not even aware of the GFD procedures or had been told by supervisors to disregard them.[41] In Walgreens' own words, the audit "Results were unfavorable."[42]

---

[36] *See, e.g.*, P-19629.

[37] P-25492_000014-17.

[38] P-15085_00006.

[39] P-20803_00001.

[40] P-15085_00009.

[41] *E.g.*, P-19584_00041-42.

[42] P-15085_00006; P-17180.

52. A review of checklists produced in the San Francisco litigation reveals similar—or greater—non-compliance. Between 2013 and 2016, the compliance rate was just 27%, meaning that pharmacists did not complete the checklist for approximately three out of every four TD prescriptions.[43]

2. Walgreens Did Not Use Its Data to Prevent Diversion

53. For decades, Walgreens has been among the largest pharmacy chains in the country. It possesses a vast amount of dispensing data and other information collected from its individual pharmacies. Walgreens also has robust data from vendors such as IQVIA/IMS, LexisNexis, and Medispan.[44]

54. Walgreens should have been analyzing that data to identify dispensing and prescribing trends, among other things, and using that information to strengthen its controls against diversion. At certain points, Walgreens conducted just this kind of analysis of pharmacies, pharmacists, and prescribers (proving its feasibility), but it opted to use the data primarily to increase sales and not to empower its pharmacists or encourage better due diligence.

55. On the pharmacy level, Walgreens had the ability to assess its stores' dispensing trends and to compare their overall volume, changes in volume, proportion of controlled substances or frequently diverted drugs to total prescriptions, and percentage of cash prescriptions.[45] A 2013 list of the "Top 500 Potential Stores" at risk for oxycodone dispensing is one example of such an analysis.[46] But, as shown in another example, Walgreens appears to have used those metrics primarily to target stores with *low* oxycodone dispensing and, in 2010, asked supervisors to "look at stores on the bottom end" of oxycodone prescribing and questioned "[a]re we turning away good customers?"[47]

---

[43] P-29849.

[44] P-28445_00008-09.

[45] P-25699_00001.

[46] *Id.*

[47] P-19543_00001.

Supervisors and district managers were instructed to review the low dispensing stores and to use "CEs" from Walgreens to help educate pharmacists.[48] (Notably, some CEs provided by Walgreens around that time were sponsored by opioid manufacturers, including Purdue and Endo.[49])

56. A similar analysis was conducted for individual pharmacists. Since 2013-14, Walgreens has used "automated quer[ies]" of its "enterprise data warehouse" and runs reports, known as "GFD Opportunities reports," generated from data on its individual pharmacies and pharmacists.[50] A "GFD Opportunities" tool included information such as Cash rank, Oxycodone IR rank, "target" drug quantity rank, and target drug rate rank.[51] Walgreens thus knew which pharmacists filled more controlled substances prescriptions than others. It appears, however, that Walgreens used the "Opportunities" report only for determining whether to provide "coaching" to pharmacists filling lower volumes of prescriptions.[52]

57. Even after its $80 million settlement with the DEA, in 2014, Walgreens' RX Integrity department created a "Pharmacist Controlled Substance Dispensing Opportunities" tool to "identify pharmacists that are dispensing a low rate of controlled substances," and help pharmacists "feel more comfortable in filling controlled substances."[53] This specifically focused on pharmacists dispensing low rates of opioids like "hydromorphone, oxycodone, methadone [and] hydrocodone," and the drugs comprising the rest of the "holy trinity" or other "cocktails," such as "carisoprodol [and] alprazolam."[54]

---

[48] *Id.*

[49] P-17193; P-19690.

[50] P-28445_00010-12; *accord* P-25700_00018-23.

[51] P-25700_00018-19.

[52] *Id.*; P-28445_00010-12; P-28446_00009-10.

[53] P-19607_00002.

[54] *Id.*

58. Walgreens also had the ability to analyze prescribing patterns in its data as well as feedback collected in visits to local stores.[55] For example, in 2012, Walgreens prepared a "Prescriber Index" that analyzed oxycodone prescribing by particular individuals, including out-of-state prescriptions, percentage of cash payments, and other detailed information.[56] Documents show that Walgreens created similar prescriber indexes for many months, but, as described below, those indexes were available only to corporate users.[57]

59. This was a theme for all of Walgreens' data analytics—even when the analyses were conducted, they were not consistently used to prevent diversion. The Rx Integrity manager in charge of Western operation (including California) confirmed as much. He explained that, as described above, as of at least 2014, Walgreens was "creating an internal portal that had reports and data" on outlier pharmacies and suspicious prescribers. Walgreens had the tools to collect and analyze its data in sophisticated ways and, on occasion, utilized those tools. The problem is that, instead of using the analysis to encourage more effective due diligence, Walgreens withheld the data from pharmacists and store-level employees because Walgreens "did not want to cloud the pharmacists' decision whether or not to fill or not to fill a prescription."[58]

60. Indeed, prior to 2020, Walgreens did not make any controlled substance metrics available to pharmacists for specific prescribers.[59] It had no dedicated field in its system for pharmacists to note patterns of red flags for specific prescribers, including frequent cocktail prescriptions,[60] or consistent prescriptions for the same patient or for several different patients.[61]

---

[55] P-15315_00009-14.

[56] P-25503.

[57] P-19573_00007.

[58] Stahmann NM AG Dep. 67-68, 79-80.

[59] CT3 Arends Dep. 90.

[60] *Id.* at 123.

[61] *Id*. at 124.

61. The few efforts that Walgreens did undertake to use its data to improve due diligence were short-lived. In December 2012, for example, Walgreens developed a "Prescriber sanction pilot project."[62] The project yielded significant insights. Specifically, "data provided by LP Analytics" showed a "Prescriber Dashboard" with three months of information about opioid drugs prescribed, age and location of patients, and prescribing volume.[63] Walgreens determined, for example, that for one "[c]ash only prescriber," 65% of prescriptions were for oxycodone, and a full 92% of prescriptions were for controlled substances.[64] Walgreens had the ability to, and did, create charts and a map to provide a visual representation of its investigation.[65] And yet, not long after the pilot was created, Walgreens shut it down.[66]

62. Very recent changes illustrate ways in which Walgreens could and should have been using the data. For example, in 2019, Walgreens described adding to its system a button on which pharmacists or staff could click to directly access a patient's history of controlled substances dispensing in the Patient Profile, and also to document a denial tied to a specific patient without an Rx number.[67] A monthly "Store Index" report and "Top 100" store report also existed.[68] According to a "DEA Board Briefing Document," Walgreens was also making additional "indexing efforts" to include drugs other than oxycodone, which efforts included "trending data," hydrocodone, two drugs commonly abused with opioids (Alprazolam and Carisoprodol), as well as "top risk Prescribers, Patients, and Pharmacists."[69] The extent to which these tools have now been implemented

---

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] *Id.*

[66] Stahmann NM AG Dep. 133-34.

[67] P-25753_00002.

[68] P-25734_00002.

[69] *Id.*

is not clear; what is clear is that these tools could and should have been developed and utilized years ago to prevent diversion.

3. Performance Metrics Discouraged Due Diligence.

63. Walgreens' performance metrics focus heavily on increasing prescription volume and decreasing customer wait times at each store. These goals come into conflict with pharmacists' corresponding responsibility to protect against diversion. A pharmacist pressured to work too quickly is at risk of missing red flags and is discouraged from investigating any red flags he or she does identify.

64. Walgreens' corporate executives have long been aware of this issue. In February 2013, Walgreens' Director of Health & Wellness Initiatives Attainment warned a Divisional Vice President and Group Vice President of Pharmacy Operations that "Fatigue and sustainability of our pharmacists is a real concern. We're asking them to do a lot but how long can they continue?"[70] Nevertheless, a month later, in a memo regarding policy changes in response to DEA enforcements actions, Walgreens kept up the pressure, telling pharmacy staff "[Good Faith Dispensing] concerns do[]n't relieve you from trying to attain the numbers that have been set for you."[71] Walgreens even created a tool to detect pharmacists who were dispensing too few opioids.[72]

65. The focus on prescription volume and speed continued. For years, Walgreens had a color-coded tool called a "PhLOmometer" to encourage pharmacists in real time to fill prescriptions faster.[73] A 2016 store leadership slide presentation also shows that managers regularly compiled prescription volume and wait time metrics to review with their pharmacists.[74] Numerous employee reports and surveys show that these metrics created high stress and unsafe work environments.[75] Internal feedback from

[70] P-27333_00002.
[71] P-00060_00002.
[72] P-19607_00002.
[73] P-23078_00002.
[74] P-23077_00022-23.
[75] P-20793_00034.

pharmacy managers showed that they were "[s]truggling to keep our heads above water let alone manage."[76]

66. To increase store prescription volume and dispensing speed, Walgreens tied compensation to its performance metrics. Its "Pharmacy Manager Bonus Program" and "Staff Pharmacist Bonus Program" both instruct that "[t]he best evidence of a well-run pharmacy is the increase in prescriptions and pharmacy sales."[77] For years, Walgreens' bonuses depended on the total number of prescriptions a store filled. Walgreens only agreed to exclude controlled substances from bonus calculations beginning in 2014 as part of the 2013 DEA settlement. But any metric that counts prescriptions works to discourage due diligence because time spent investigating the legitimacy of an opioid prescription is time a pharmacist cannot spend filling other prescriptions that factor into the metric.

67. Finally, in 2019, Walgreens retained Tata Consultancy Services to analyze its pharmacy systems and workflow. After significant on-the-ground research and pharmacist interviews, Tata included a slide on "errors resulting from stress" in a draft presentation for Walgreens that explained: "We heard multiple reports of improper behavior" that was "largely attributed to the desire" to meet a Walgreens metric known as "*promise time*," which ensures that patients get prescriptions filled within a set amount of time.[78] A later slide on "User Perception" reported that "proper procedures are sometimes skirted or completely ignored due to worries of meeting promise time."[79] Rather than confront this very real problem, Walgreens executives instructed Tata to delete the "high stress" slide entirely, and to rewrite the User Perception Slide to read as follows: "Procedures are sometimes perceived as barriers to addressing all necessary pharmacy

[76] P-17218_00005.

[77] P-19821_00001; P-19529_00001.

[78] P-14357_00037.

[79] P-14357_00061.

tasks."[80] This is emblematic of Walgreens' pattern of ignoring or denying evidence of non-compliance and the effect on public safety.

C. Walgreens' Policy Failures Led to Diversion

1. Analysis of Walgreens' San Francisco Dispensing Data

68. In connection with the "Case Track Three" trial before Judge Polster, I analyzed the due diligence documentation, if any, for 2,000 red-flagged opioid prescriptions dispensed by Walgreens pharmacies in Ohio. I concluded that "effective due diligence was not performed on … approximately 90%" of the prescriptions "ultimately dispensed" by Walgreens. In this case, Dr. Elizabeth Park conducted a similar review of several thousand opioid prescriptions dispensed by Walgreens in San Francisco and similarly concluded that "fewer than 5% contained evidence of due diligence that [was] … adequate to resolve the flag (or flags) identified."[81]

69. While I did not personally review the subset of prescriptions for which Walgreens produced all due diligence materials in this case, I did analyze statistics compiled from Walgreens' San Francisco dispensing data as well as certain individual prescriptions. Based on this review, I concluded that Walgreens stores in San Francisco repeatedly filled prescriptions with numerous red flags.

70. Of the approximately 2.5 million prescriptions in the data produced, nearly one third (32.13%) had not just one, but multiple red flags:

[80] P-14370_00039.

[81] Elizabeth Park Report at 22.

Summary of Dispensing Red Flag Analysis
San Francisco County, CA
Nonrecurrent - Flagged Multiple Times

Defendant	Walgreens	
Total # of Opioid Prescriptions	**2,478,103**	
Opioid Prescriptions Flagged - 2+ Methods	796,224	32.13%
Opioid Prescriptions Flagged - 3+ Methods	348,282	14.05%
Opioid Prescriptions Flagged - 4+ Methods	132,199	5.33%
Opioid Prescriptions Flagged - 5+ Methods	42,655	1.72%
Opioid Prescriptions Flagged - 6+ Methods	11,608	0.47%
Opioid Prescriptions Flagged - 7+ Methods	2,895	0.12%
Opioid Prescriptions Flagged - 8+ Methods	598	0.02%
Opioid Prescriptions Flagged - 9+ Methods	100	0.00%
Opioid Prescriptions Flagged - 10+ Methods	10	0.00%
Opioid Prescriptions Flagged - 11+ Methods	1	0.00%
Opioid Prescriptions Flagged - 12+ Methods	0	0.00%

Notes

Defendant	Date Range
Walgreens	1/2006 - 6/2020

71. Based on this review, it is clear to me that Walgreens has a history and pattern of filling prescriptions that trigger multiple red flags. Dr. Park's conclusion that Walgreens failed to identify, resolve and document most red flags before filing those prescriptions in San Francisco is consistent with my findings in Ohio. That finding is particularly alarming given the volume of prescriptions with multiple red flags. Given the expected danger of diversion, it is reasonable to believe that when so many "red flag" prescriptions are dispensed without due diligence to clear the suspicions, a substantial number of such prescriptions were likely diverted.

2. Walgreens Filled Tens of Thousands of Opioid Prescriptions for Questionable Prescribers, Many of Whom Ultimately Lost Their Licenses

72. In addition to the aggregate dispensing data review discussed above, I analyzed San Francisco Walgreens dispensing trends for certain physicians with suspicious prescribing patterns, many of whom were disciplined by regulators for their negligent prescribing. Below I discuss five prescribers who, individually and collectively, illustrate how Walgreens' policies and procedures failed to guard against diversion.

73. The first is **Dr. Guido Gores**, who, at one time, was the second highest opioid prescriber in San Francisco and in the top 1% nationwide.[82] In February 2021, Gores surrendered his license in response to allegations that he prescribed opioids to patients before examining them, prescribed opioids contributing to a patient's death, and committed other acts of gross negligence.[83]

74. Walgreens should have been, and in fact was, aware of Dr. Gores' suspicious prescribing for years. Between 2006 and 2020, Walgreens filled nearly 10,000 opioid prescriptions from Dr. Gores,[84] of which *approximately 82%* triggered at least one red flag.[85]

75. As early as 2012, Walgreens corporate actually recognized through data analysis that Dr. Gores was an outlier whose opioid prescriptions stood out as particularly risky.[86] As noted, however, Walgreens corporate decided not to share that information with its pharmacies for fear that it would "cloud the pharmacist's" judgment.[87] Even without the help of the data that management withheld, some pharmacists figured it out, and by 2019, two separate Walgreens pharmacies (1301 Market St. and 1300 Bush St.) had, of their own initiative, stopped filling Dr. Gores' controlled substance prescriptions.[88] But, because Walgreens lacked a method to escalate such concerns systematically, other San Francisco Walgreens kept filling.[89]

---

[82] Lacey Keller Report ¶¶ 54-55.

[83] P-22297.

[84] As the result of further analysis, this figure, and other similar figures in this section of my Declaration, have been refined slightly from those used in my reports. For example, benzodiazepines prescribed with opioids as part of a risky drug cocktail are no longer counted as additional flagged prescriptions.

[85] P-28506b.

[86] P-27369; *see also* P-27367 and P-06999.

[87] Stahmann NM AG Dep. 68:14.

[88] P-27265; P-27532.

[89] P-28506b.

76. In September 2019, Walgreens' RX integrity team learned the DEA was investigating Dr. Gores' opioid prescribing.[90] Walgreens' San Francisco pharmacies continued to fill another 400 of his opioid prescriptions for an additional nine months.[91]

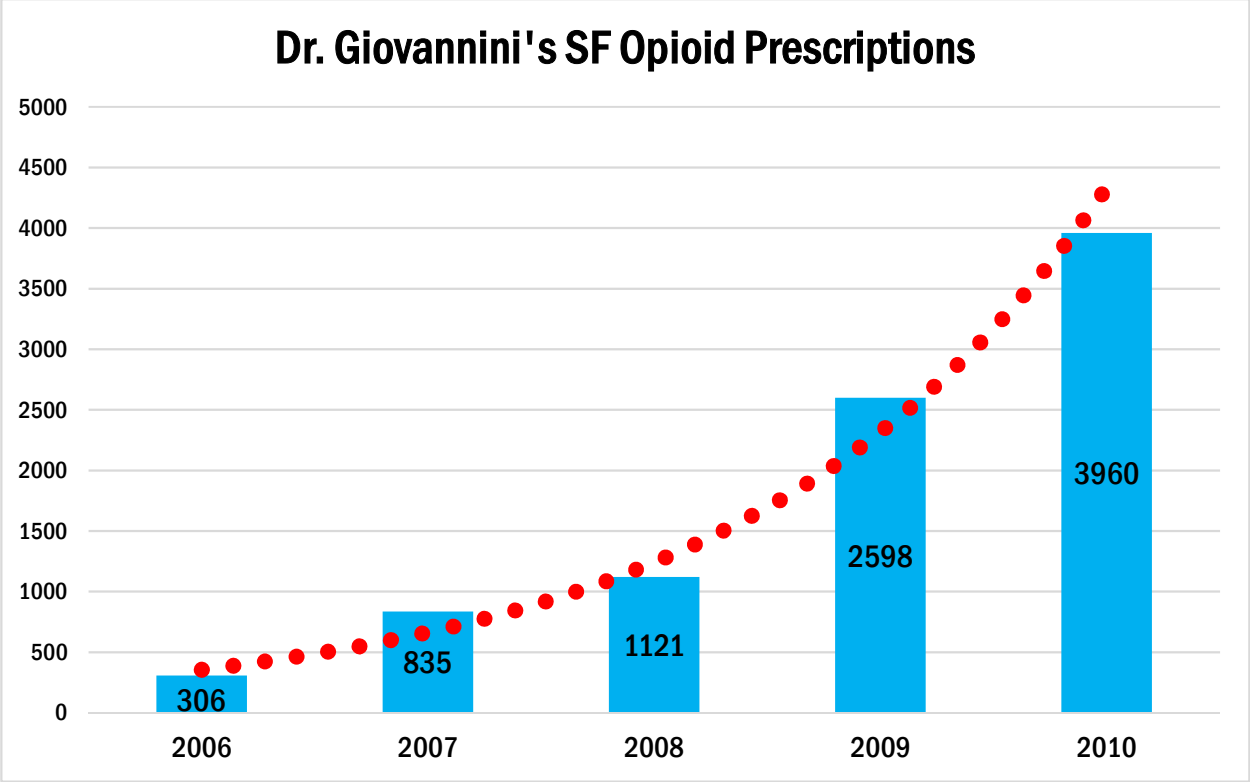
77. A close analysis of a few prescriptions indicate just how suspicious Dr. Gores' prescribing was and how ineffective Walgreens' controls were. For example, one of his prescriptions hit 10 out of the 14 red flags, yet was still dispensed in 2018 (901 Hyde St.). Another pair of his highly-flagged prescriptions from 2017 were written and filled at 1300 Bush St. for the same patient on the same date at the same store. According to the dispensing data, both were purchased in cash. Both drugs were also "Target Drugs" that should not have been dispensed without a completed TDGFD checklist. But based on my review, it appears the pharmacist completed a checklist for only one of the two prescriptions. Furthermore, the checklist contradicts the data, stating that the prescription was *not* purchased with cash.[92] This same store filled nearly 100 opioid prescriptions for this patient, two dozen of which were accompanied by a benzodiazepine, written by Dr. Gores (or his practice partner, Dr. Emily Fung), approximately half of which were purchased with cash. In a typical month, this one store dispensed 880 pills to this one patient (360 hydromorphone 8mg, 420 methadone 10mg, 100 diazepam 10mg).

78. **Dr. Andrew Giovannini**'s story is similarly egregious. Dr. Giovannini was an extremely high-volume prescriber, ranking 16th in the nation in 2010.[93] In May 2012, Giovannini surrendered his medical license for gross negligence and excessive opioid prescribing for five different patients.[94]

79. As with Dr. Gores, Dr. Giovannini's suspicious prescribing should have been and, in fact, was known to Walgreens long before then. In just five years from 2006 to 2010, San Francisco Walgreens filled more than 9,000 of Dr. Giovannini's opioid

[90] P-27532.
[91] P-28506b.
[92] P-27446.
[93] Keller Report ¶ 68.
[94] P-27514.

prescriptions.[95] Remarkably, despite the fact that Dr. Giovannini had been practicing internal medicine since 1965, the volume of his opioid prescriptions increased *thirteen-fold* from 2006 to 2010:[96]



80. This volume of prescribing should have been identified by corporate headquarters and guidance should have been provided to pharmacists concerning these patterns. Walgreens' own policies confirm that such extreme increases in volume "should alert a pharmacist to questionable circumstances,"[97] making its failure to provide such data to its pharmacists particularly inexcusable. In addition, an astounding 94% of those opioid prescriptions triggered one or more red flags.[98] Initially, almost a quarter of them were part of a dangerous "cocktail" with a benzodiazepine, and this percentage, too, doubled to more than 50% by 2009.[99] I also located 12 oxycodone prescriptions written by

[95] P-28506b.

[96] *Id.*

[97] P-15119_00001.

[98] P-28506b.

[99] *Id.*

Dr. Giovannini and filled at various Walgreens stores in San Francisco—3398 Mission St., 1189 Potrero Ave, and 4129 18th St.—that hit at least 9 out of the 14 red flags.

81. It appears that some pharmacists took notice. Dr. Giovannini's "Prescriber comments" in Walgreens' dispensing data included comments like "**MONITOR CII**" and "BEWARE HIS PATIENT IS FILLING OXYCONTIN CASH RX OF THOUSANDS OF DOLLARS." As summarized by former Walgreens pharmacist Rebecca Gayle, "most everyone in [San Francisco] knew he was a real fishy doctor to fill for" even "a few years" before he lost his license.[100] Yet I have seen no evidence that Walgreens management made any efforts to implement a hard or soft prescriber block or to otherwise advise its pharmacies in the area to carefully review the thousands of Dr. Giovannini prescriptions that they continued filling.

82. Walgreens' corporate office also appears to have effectively ignored the suspicious prescribing practices of San Francisco doctor **Collin Leong**. Thousands of his opioid prescriptions were filled at Walgreens before he surrendered his license in 2014 (and ultimately pled guilty to felony charges) for selling opioid prescriptions to patients with no examination and no medical justification.[101]

83. Between 2006 and 2013, Walgreens' pharmacies in the Bay Area filled almost 2,200 of Dr. Leong's opioid prescriptions, with almost 79% triggering red flags.[102] Pharmacist Rebecca Gayle testified that she found his prescriptions particularly suspicious and tried to warn other pharmacists in her area about him, but lamented that Walgreens offered no mechanism to do so in a systematic or comprehensive manner.[103] Meanwhile, a prescriber analysis that Walgreens itself conducted in 2012 showed that Dr. Leong was in the top 20 in the country for average monthly sales of various target opioids, with

[100] Gayle Dep. 96:15-97:12; *id.* at 92:4-100:22.

[101] P-28506b; P-27610; P-27568.

[102] P-28506b.

[103] Gayle Dep. 69:15-72:1, 100:24-102:21.

activities that stood out as particularly risky.[104] By early 2013, internal Walgreens documents even show that "a lot of stores had tagged [his] name as do not fill for controls" and one asked corporate leadership to "broadcast" information about him to all regional stores.[105] I have seen no evidence that Walgreens did so. Even after compiling data and receiving repeated warnings, Walgreens filled more than a hundred of Dr. Leong's opioid prescriptions in the Bay Area before he ultimately surrendered his license.

84. **Dr. John Pierce** is another example. He, too, was a very high-volume opioid prescriber. Of the more than 10,000 of his opioid prescriptions that Walgreens dispensed in the Bay Area, 75% triggered at least one red flag.[106] Pharmacist Rebecca Gayle noticed Pierce's suspicious prescribing around 2016, but Walgreens continued to fill thousands of his prescriptions while he continued to practice.[107] As Walgreens' own emails acknowledge, by no later than August 17, 2019, Dr. Pierce was placed on a BOP Controlled Substances Restrictions List as a result of his negligent opioid prescribing.[108] Notwithstanding this, and his surrender of his license on December 31, 2019,[109] Walgreens' dispensing data shows that the company continued filling his prescriptions through April 16, 2020.[110] This violated the pharmacy standard of care as well as Walgreens' agreement with the DEA—reached after similar incidents—to maintain procedures to prevent its pharmacists from filling prescriptions from prescribers with invalid registration numbers.[111]

85. **Dr. Ray Seet** provides the final illustration. Although Dr. Seet worked in Marin and Sonoma, Walgreens' San Francisco pharmacies should have been particularly

---

[104] P-27369.
[105] P-27533_00001.
[106] P-28506b.
[107] Gayle Dep. 75:11-76:12, 79:4-17.
[108] P-28997_00001-02.
[109] P-28430.
[110] P-28506b.
[111] P-15_00006, P-15_00015.

attentive to his prescriptions. Indeed, 98% of Dr. Seet's nearly 900 opioid prescriptions filled at San Francisco Walgreens stores triggered at least one red flag.[112] Dr. Seet was cited by the California Medical Board as early as 1996 for various instances of medical malpractice resulting in license probation. Walgreens also recognized as early as 2012 that Dr. Seet was a very high-volume prescriber whose prescriptions stood out as particularly risky.[113] Again, Walgreens did not utilize this analysis to improve due diligence or minimize diversion. Instead, Walgreens filled almost a thousand additional prescriptions in 2013. Indeed, even after Dr. Seet's medical license was revoked for grossly negligent prescribing (sometimes without medical examination), Walgreens continued to fill Dr. Seet's opioid prescriptions for another month.[114]

86. These are just examples, but—in combination with the sheer number of red flags in Walgreens' San Francisco dispensing data—they provide strong evidence that Walgreens' failure to maintain effective controls likely resulted in significant diversion of prescriptions that were not issued for a legitimate purpose.[115]

D. The Experiences of Walgreens' Own Pharmacists Confirm Walgreens' Failures.

1. Testimony of Walgreens' Pharmacists

87. I have reviewed the testimony of several current and former Walgreens pharmacists who were deposed in this case. Their testimony tells a compelling story that reinforces many of the conclusions I have reached about Walgreens' failures under the CSA. Below I highlight a few recurring themes and illustrative testimony.

[112] P-28506b.

[113] P-27369; *see also* P-27367; P-06999.

[114] P-27609.

[115] Craig McCann Report at 87-97; McCann Rebuttal Report at 15-18.

Theme	Illustrative Testimony
Pressure to fill prescriptions quickly at the expense of adequate due diligence	• Gayle: "There was a pressure to fill, fill, fill and that was what the company cared about most" (16-17), and she "would get feedback to shave down time on [Board of Pharmacy] law requirements to focus more on filling prescriptions" (32). • Mathews-Porter: "You have to pick and choose your battles" when conducting due diligence on prescriptions because of the volume of prescriptions (66). • Yagar: Fulfilling his job requirements in a high-pressure environment could be "unsafe" (40-41). He testified that "it's the metrics" that create the pressure to fill (54). • Gerspacher: In his experience, it was difficult to perform his job safely while racing to meet unreasonable corporate metrics (20-22).
Pharmacists incentivized not to conduct adequate due diligence by Walgreens corporate metrics	• Mathews-Porter: Customer feedback metrics affected pharmacists' performance reviews, and "every time we refused a prescription, it resulted in a [customer] complaint" (29). As a result, "the cycle of how it went" was that pharmacists were penalized for conducting more due diligence (122). • Yagar: Because his bonus is determined by filling more non-controlled substance prescriptions, any time spent conducting due diligence on controlled substance prescriptions reduces time to fill those non-controls (29-30). Stores receive a customer feedback score—"a constant topic of discussion" given monthly (151), which was negatively affected when pharmacists refused to fill prescriptions (152-55).
Understaffing, which hindered greater prescription due diligence and impacted patient safety	• Gayle: Over the years she worked at Walgreens, "our technicians, staff and hours would be cut constantly" (21); staffing was so inadequate that pharmacists were skipping their lunch and breaks (19). • Mathews-Porter: Staffing levels went down over time at Walgreens (66). Eventually, "[y]ou're basically by yourself making decisions, and having another pharmacist would always be safer" (70). • Yagar: Understaffing impeded pharmacists' ability to conduct adequate due diligence and led him to try to decrease the number of controlled substance prescriptions filled at his store (60-61).

Theme	Illustrative Testimony
Dispensing practices controlled by non-pharmacist managers who prioritized profit over compliance—and, in fact, disciplined pharmacists for conducting due diligence	• Yagar: Was berated by multiple store managers for refusing to fill a suspicious opioid prescription, which the store manager then directed the pharmacy to fill (131-45); • Gayle: "Our district managers were not necessarily pharmacists" and thus did not "have a full understanding of the responsibilities … of being a licensed pharmacist," creating a conflict of interest between management and pharmacists (129-30). Her manager "threatened … a performance improvement plan writ[e] up if I was too slow" (176). "[I]f you spent too long doing things that didn't result in dispensing of a prescription … your relationship with your manager would be negative" (35). • Kamali: Management "would not back [pharmacists] up" for decisions related to due diligence, and, in fact, she alleges she was terminated for refusing to fill suspicious opioid prescriptions (58).
Inadequate due diligence policies and training	• Yagar: Checklists did not apply to combination medications such as Vicodin and Norco (80-81). Any comments made on these checklists were not inputted into the computer system and made accessible to other pharmacists (84). Walgreens did not have a mechanism for ensuring consistent due diligence across pharmacies (76-77); indeed, one week prior to Yagar's deposition, he refused to fill a suspicious opioid prescription that was subsequently filled by another Walgreens location in the area (86-87). Before 2013, refusals to fill were likely not documented in Walgreens' central computer system (89-90). The GFD policy was inadequate and encouraged the pharmacist to act "like a robot" (115-18). Changes to the GFD policy over time made it worse, including by narrowing the scope of red flags (125-26). • Mathews-Porter: Regarding opioid dispensing, "I wanted help. I wanted support. I wanted guidance. I didn't have it" (98). • Gerspacher: Did not recall any training on either identifying or resolving red flags aside from "a one-page brochure that you kind of read through and then you checked a box in the training module" (30-31); training

Theme	Illustrative Testimony
	in subsequent jobs highlighted the inadequacy of Walgreens' training (31-32).
Walgreens did not provide information to pharmacists about suspicious prescribers	• Gayle: Did not remember "getting a list of suspicious prescribers to avoid filling prescriptions for or anything like that" (71). • Yagar: Received no lists of suspicious prescribers from management. To the contrary, received "an email" from management telling pharmacists not to "deny[] prescriptions" from a physician later convicted for fraudulent prescribing and second-degree murder, saying "these are good scripts" (94-95, 98-101). • Gerspacher: Never received information from management regarding suspicious prescribers; such information would have resulted in better diligence on opioid prescriptions (45-46). • Mathews-Porter: Did not recall alerts about suspicious prescribers (108-10).
No effective way to share concerns about suspicious prescribers, and Walgreens sanitized the prescriber comments in its computer system	• Gayle: "What I did at my stores was … write [] names on a Post-it note … then I would try to tell the other pharmacists who worked on Mission Street about those prescribers" (69-70). • Kamali: Negative comments about prescribers in computer system "were permanent until one day I noticed they were all wiped out" (69). Believes management wiped prescriber comments "because they didn't want us to have access to that, and they wanted us to fill the prescriptions" (70). • Yagar: "[T]ypically what I do is I write down on a piece of paper alphabetically different doctors where I see curious prescribing habits" (91), because making notes in computer system about potentially suspicious prescribers "[has] been discouraged. You could put comments in the prescriber's file, and they get taken out" (102-03).

2. Internal Complaints

88. I reviewed a selection of incident reports submitted through Walgreens' legacy Asset Protection Information System, which was retired in 2019. The reports further confirm that pharmacies were understaffed, and pharmacists faced tremendous

pressure to prioritize filling prescriptions quickly and without adequate due diligence. Given that Walgreens employees have alleged retaliation (including termination) for raising concerns about improper due diligence, I would expect that many employees are afraid to come forward, and these complaints are likely under-representative.[116] Moreover, I understand that this is a single database and that Walgreens did not search for all relevant internal complaints in this litigation. Nevertheless, below I have excerpted notable quotations from an illustrative sample.

Year	Location	Excerpted Quotes	Exhibit No.
2011	Texas	Pharmacy Manager … has been bypassing safety checks with the customer's prescriptions … to meet the promise time.	P-27296
2012	Oklahoma	The caller said [the physician] was running a "pill mill." … Management was trying to fill every prescription possible after an account was lost. The caller did not want to be pressured to fill prescription from [the prescriber] knowing the circumstances. The caller feels a company wide policy should be established to not fill prescriptions from [the prescriber]…. It's a matter of time before someone overdoses and the caller did not want Walgreens to be the company that filled prescriptions that killed somebody.	P-27297
2012	San Francisco Bay Area	[T]he pharmacy has been short staffed. … The pharmacy has a volume of 300 scripts per day and there are only two individuals on staff to take care of this. … They can't service customer[s] properly and are at a higher risk to make mistakes because they are constantly rushing to try to get caught up.	P-27304
2013	Colorado	A patient requested a refill of a controlled substance which [the pharmacist] evaluated to be to[o] soon in her professional judgment. … [T]he prescriber went above [the pharmacist]'s head and complained to her supervisor…. [The supervisor] attempted to convince her that she should just dispense the prescription to the patient AGAINST HER PROFESSIONAL	P-27303

[116] *See Simms v. Walgreen Co.*, No. 19-565, Dkt. 1 (D. Me. Dec. 16, 2019) ("Simms disregarded this unprofessional and unlawful directive from his supervisor and took the necessary steps to prevent the potential introduction of fentanyl into an illicit drug distribution network. Walgreens fired Simms for taking these appropriate actions . . . ."); *Trahan v. Walgreen Co.*, 18-cv-2688, Dkt. 1-1 ¶¶ 7-8, 10 (W.D. Tenn. Oct. 3, 2018) (alleging termination in response to complaint to Board of Pharmacy regarding manager's interference with due diligence); *O'Donnell v. Walgreen Co.*, No. 19-cv-3903, Dkt. 1 (N.D. Ill. June 11, 2019) (alleging termination for refusing to fill suspicious opioid prescriptions, among other things).

Year	Location	Excerpted Quotes	Exhibit No.
		JUDGEMENT. … [He said] he is on the Board of Pharmacy so he knows what will happen, so she won't get in trouble. When [she] continued to refuse, [he] asked if there was any other pharmacist on duty who would be willing to dispense the prescription. … [I]t appears as though [the supervisor] attempted to coerce [the pharmacist] to dispense the controlled substance prescription against her professional judgment, which is both against Colorado law and Walgreens policy.	
2013	California	Caller … reported that … Store Manager … violated Walgreen's National Target Drug Good Faith Dispensing Policy, when she overrode and removed his decision not to dispense a prescription to customer…. [The pharmacist] examined the customer's prescription history and noticed that within the last two months the patient had moved his/her prescription from Walgreens to Wal-Mart and back to Walgreens. … [T]his was a red flag…. [The manager] told him that she could not afford to lose a customer who spends $6,000 a month in her store.	P-27298
2013	Arizona	[Pharmacy manager] again insisted that the [Good Faith Dispensing] policy does not apply to his store. … [Pharmacy manager] responded that Walgreens does not want me to follow that policy in practice. Dispensing medications ASAP was the compan[y's] priority and I was to dispense the medications immediately and contact the prescriber for verification and complete [Good Faith Dispensing] form later at a more convenient time. [Pharmacy manager] said that our GFD files would never be audited by the company, so it was OK to do so in apparent violation of policy. … [Pharmacy manager] replied that Walgreens does not expect pharmacists to follow the letter of the law. [Pharmacists] are paid to dispense mediations as long as we are not contributing to diversion….	P-27300
2014	Florida	Staff is being pressured to fill all narcotic prescriptions by pharmacy manager. Pharmacists refuse to partial fill c-2s as well as deny[] narcotics based on good faith[.] [W]hen this happens the pharmacy manager creates a negative work environment.	P-27288 P-27289
2014	California	The lack of adequate staffing pos[es] risks to patient safety and standards of customer service.	P-27327

Year	Location	Excerpted Quotes	Exhibit No.
2015	Florida	[The pharmacist] explained that Store Manager … and Pharmacy Manager … receive a bigger bonus if they have prescription sales. … [The caller] feels pressed by [the managers] because they want her to fill narcotic prescriptions without verification first.	P-27305
2015	Southwest Region	Vice President … informed District Manager … that all Pharmacists would be required to work twelve hour days without lunches or breaks. … Walgreens could have more prescription errors … because the Pharmacists will be overworked.	P-27328
2017	Oregon	A friend of mine, a pharmacy manager from a different store, told me yesterday that [promise time] is one of the key performance indicators used to determine annual bonuses for pharmacy supervisors, store managers and pharmacy managers. … [T]his is against the rules of the [O]regon [B]oard of [P]harmacy regarding keeping productivity quotas.	P-27292
2017	Illinois	Store M[anager] spoke badly about the staff [pharmacist] stating that she is the reason the store[']s verified by promise times are bad…. The staff [pharmacist] is the one who catches all the medication errors…. How can this company care more about numbers than patient safety[?]	P-27293
2018	California	[The pharmacist] accused [two store managers] as being extremely intimidating and persuasive in questioning the refusal of the prescription…. [He] claimed that Walgreens allowed managers to do this and this caused an institutional conflict of interest where controlled prescriptions are being filled for financial gain without questioning the legitimacy of the prescription. [He] made claims of retaliation due to managers having authority over pharmacist[s] to determine who is promoted to a pharmacy manager, and mentioned when he applied for pharmacy manager he was not promoted.	P-17250
2019	San Francisco	[T]he increasing workload is becoming dangerous. … [H]e is concerned that because of the busy overworking there is an increasing chance a mistake will be made with medications that could cause harm to a customer.	P-27325
2019	Arizona	[The] Promise Time [performance metric] has a target percentage goal that is not realistic giv[en] the staffing level at most Walgreens. … [We are] focused on churning prescriptions at an unsafe speed. … I hope that my concern wi[ll] be seen by the Board of Directors. We are putting profits above the safety of our customers. When Ford and Boeing did that it did not pay off. I hope Walgreens will do what is right/ethical and remove this metric immediately before lives are lost and litigation ruins this great company.	P-27295

III. CONCLUSIONS

89. Walgreens failed to maintain effective controls to guard against diversion of prescription opioids.

90. Walgreens failed to meet standards of pharmacy practice with respect to the dispensing of dangerous, controlled substances, including prescription opioids.

91. Walgreens failed to timely implement and apply necessary controlled substance diversion policies across its pharmacies.

92. Once controlled substances diversion policies were developed, Walgreens failed to monitor and enforce the policies across its pharmacies.

93. Walgreens failed to provide its pharmacists with necessary data, information, and tools to help them fulfill their corresponding responsibility.

94. Walgreens implemented dispensing policies that obstructed its pharmacists' access to relevant information and impeded their ability to take the time needed to perform due diligence on red flag opioid prescriptions.

95. These failures likely resulted in the diversion of significant quantities of opioids in and around San Francisco.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 8th day of May, 2022 in San Francisco, California.

Carmen A. Catizone, M.S., R.Ph., D.Ph.